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Description

**Laminate, process for its production, and the use of a laminate in particular
as a medical backing material**

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The invention relates to a laminate, a process for its production, and its use in the hygiene and medical sectors, in particular as a backing material for first-aid
15 wound pads and roll plasters and other applications in which the elasticity of the laminate and an excellent bond are advantageous.

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Laminates used as medical backings have already been described.

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For example, EP 0 446 431 has disclosed a backing material for medical plasters which is formed from a laminate which in turn is composed of a first polymer film layer, a second film layer produced on the first polymer film layer, and a third layer of a macroporous textile material, to some extent embedded within the second layer and thus anchored therein. The first-mentioned layers are preferably composed of polyurethane, and the textile material is in particular formed by a polyester nonwoven or by a lattice tulle.

The backing material may then have a self-adhesive, skin-compatible coating, preferably on the textile side of the material.

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WO 97/42922 has disclosed a production process for a laminate which on one side has a self-adhesive coating. For this, a polymer film is melted on a thermoplastic woven or nonwoven by the action of heat, where the heat does not act over the entire surface. A self-adhesive coating is moreover applied to the

woven side or nonwoven side, and a wound pad may in turn be placed onto this coating.

A frequent disadvantage of the known coatings is that the laminates delaminate
5 under mechanical stress, and this is particularly the case for medical products. It
is also possible that the laminates are not of a single material and therefore
production residues which arise, or sheets of used products cannot be recycled.

An object of the invention is therefore to provide a laminate which avoids the
10 disadvantages known from the prior art. It should be cost-effective to produce and
not present ecological hazards, and should also be pleasant to use.

This object has been achieved by means of a laminate as described in Claim 1.
The subject matter of the subclaims here is advantageous embodiments of the
15 laminate, a process for its production, and its use, in particular as a medical
product.

The invention proposes a laminate composed of at least a first layer of an elastic
polymer film and of a second layer of an elastic textile sheet, where the finished
20 laminate has a microscopic and/or macroscopic embossed effect.
The textile sheet is preferably a nonwoven material or a woven.

The materials used as the elastic polymer film are in particular homopolymers of
polyethylene, copolymers of ethylene and an α -olefin with a carbon number of
25 from C₄ to C₁₀, such as LDPE, LLDPE, VLLDPE or ULLDPE or polyethylene,
prepared in a metallocene-catalysed process or in a „single-site-type“-catalysed
process, copolymers of EVA, ethylene-alkyl acrylate, ethylene-methyl acrylate,
ethylene-acrylic acid and ionomers, and also homopolymers and copolymers of
30 polypropylene, for example isotactic, atactic and/or syndiotactic PP, copolymers
of PP and PE, copolymers of PP and butene, and others, all preferably prepared
via Ziegler-Natta catalysis or metallocene-catalysis, and finally also mixtures of
the polymers mentioned.

In a preferred embodiment the first layer of the laminate has a structure of more
35 than one layer of a copolymer of ethylene and polar comonomers or of a mixture
of LDPE and an LLDPE, prepared by a metallocene-catalysed process (m-PE).

In another preferred embodiment the polymer film of the first layer is a copolymer of ethylene and an α -olefin having a carbon number of from C₄ to C₁₀, where the polyolefin has a melt index of from 1 to 20 g/(10 min) and a density of from 860 to
5 900 kg/m³.

In another preferred embodiment the first layer of the laminate is composed of two coextruded layers with an outer layer and a tie layer, where the tie layer is composed of pure thermoplastic polyolefins without addition of additives or
10 colorants.

The polymer film of the first layer may also comprise at least 65% of a thermoplastic elastomer.

15 The materials used for the fibres of the textile sheet are likewise the abovementioned polymers, specifically also as a mixture or as coextrudates, and also viscose and derivatives thereof, polyesters or modified polyesters and polyamides.

20 A nonwoven used for this purpose may be produced by spinbonding, meltblowing, thermobonding, wet laying, carding or weaving, or also combinations of the processes listed.

Examples of other additives which are added to the polymer mixtures are heat
25 stabilizers, UV stabilizers, antistats, antislip additives and antimicrobial or fungicidal substances..

This invention includes variations in the formulation of the polymer mixtures or in the production process which are obvious to a person skilled in the art.

30 The weight per unit area of the polymer film of the first layer is preferably from 15 to 150 g/m², in particular from 35 to 60 g/m², and/or the weight per unit area of the textile sheet is from 25 to 200 g/m², in particular from 30 to 100 g/m².

35 It is preferable for a skin-compatible self-adhesive coating to have been applied to the textile sheet side.

The following steps are used in particular in order to produce this laminate. These steps may be carried out continuously or separately, without affecting the properties of the product.

5 Mixtures of polymers with a melt index of from 1 to 20 g/(10 min) are introduced, in the form of pellets or granules, to one or more extruders, are mixed or melted there, and then form a continuous stream. (The temperature of the melt is from 175 to 330°C).

In the case of coextrusion, the stream of the polymer melt is brought together in
10 an adapter (feed block) and a coextruded melt film is formed in a slot dye. The melt film emerges from the slot dye and is cooled between two cylinders, where one of the cylinders may have been engraved, in order to give the film an embossed effect (calender unit). The nonwoven or the textile sheet is conducted between the two cylinders in such a way that the melt film is laid on the embossed
15 cylinder. The temperature of the cooling rolls here is from 10 to 65°C.

The engraving of the cooling rolls or the engraving of the surface of the cooling rolls gives the laminate particular surface properties: a microscopic emboss (from 10 to 200 µm) makes the surface soft and matt, and a macroscopic emboss (from 200 to 3000 µm) gives the film similarity to a textile. In the case of coextrusion
20 with two or more layers, the feed block process, multimanifold process or tandem extrusion coating process is used.

This "cast" process may be carried out in a similar manner using a previously produced film made from the polymers described above, where one side of the
25 film may have been embossed, and a textile sheet, where the two layers are introduced to the extrusion plant and joined together (heat-lamination) by means of a molten film made from the polymers described above.

In another preferred version of the process at least two sets of polyolefin granules
30 are each melted in an extruder and applied simultaneously in at least two layers onto the textile sheet.

If desired, one side of the laminate, specifically the nonwoven side, may be provided with a self-adhesive coating, to which a wound pad may be applied if
35 desired.

For physical perforation of the backing material coated with pressure-sensitive adhesive, a microperforation system, preferably in the form of a spiked roller, is used at elevated temperatures of from 100 to 130°C. This gives the coated backing material permeability to air.

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The laminate used according to the invention is a film-nonwoven composite with extremely high elasticity in longitudinal and transverse directions, good cushioning properties (through the use of the nonwoven) and a very agreeable soft film surface through use of a specific emboss effect.

10 Nonwoven and film here preferably have similar recovery capabilities, so that no delamination of the composite material occurs at elongations up to well over 100%.

Besides the cushioning properties of the composite material, for use as a plaster emphasis should be given to the absorption of moisture (water vapour) by the

15 nonwoven material on the side facing the skin (wear comfort).

To achieve these properties, the production of the laminate uses, inter alia, specific metallocene LLDPE grades which, in the form of sheetlike materials and in combination with the particular surface-embossed effect, give the particular feel

20 (soft and comforting) and elasticity.

Other advantages of the use of the metallocene PE materials:

a) low migration, i.e. no migration of low-molecular-weight constituents to the surface, and therefore good anchoring of pressure-sensitive adhesive compositions, and non fall-off of surface tension even after prolonged storage;

25 b) no addition of stearates necessary (BSE);

c) high purity of the polymer used (smallest traces of the catalyst used); and

d) density and polydispersity of the polymer used can be adjusted within the ranges desired.

30 The particular feel is a function of the large number of abovementioned components and processes, and also of the choice of the nonwoven material, of the PE grades in the film (LLDPE; VLDPE), of the surface-embossed effect of the film and of the textile sheet, and also of the manner in which the production process for the laminate is conducted.

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In particular the use of a 50 µm metallocene PE (VLDPE) film gives better contact between the nonwoven fibres and the PE film (via viscosity properties of the

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polymer melt) than with conventional PE grades. Consequently the film-nonwoven composite does not delaminate, even on extreme elongation.

In most laminates produced for hygiene applications (nappies) the nonwoven side
5 is used as outer side, mostly because it gives a higher-quality impression, but there is no direct benefit for the product. When the novel laminate is used as a medical backing material the nonwoven side in the product (preferably a plaster) is used as inner side. This gains the additional function of a moisture retainer if the application of the pressure-sensitive adhesive is, as is preferred, in the form of
10 spots or a grid.

This property improves the adhesion of the plaster on the skin, since film plasters usually have extremely limited adhesion when worn for a relatively long period at relatively high temperatures and atmospheric humidity (moisture accumulates under the (impermeable) film plaster and causes rapid release of the entire
15 product).

The laminate may moreover be used for the production of self-adhesive bandages or of similar products.

The particular properties of the laminate also indicate a possible use as backing
20 for a hygiene item, in particular a nappy or an incontinence product.

The material is advantageously suitable for single-use covering materials for uses associated with surgical procedures, and as a material employed in protective clothing.

25 The laminate makes it possible to save costs, since low-cost raw materials are used for the essentially single-step production process.

Compared with other thermoplastic elastomers, metallocene polyolefins are relatively inexpensive polymers.

30 The melt extrusion process is a very cost-effective process, since it is merely a modification of a casting process for producing a polyolefin film. The melt film is simply laid on a textile sheet instead of on a cooling roll.

There is no need for any additional step, unlike, for example, in off-line lamination of a previously extruded and cooled film to a textile sheet using hot-melt
35 adhesives.

Ecological considerations are also taken into account in the use of the novel laminate. The preferred embodiment of the product is produced from a single raw material, specifically pure olefins. This laminate can be recycled since a single-material product, and also any production residues which may arise and sheets of
5 used products, can be reutilized.

The particularly advantageous properties of the laminate will be described again using the figures below, and the production of an extrusion-laminated composite product will be illustrated by a number of examples, without any intention of
10 unnecessarily limiting the invention described to particular product formulations or process steps.

Figure 1 shows the layer structure of the laminate.
15 Figure 2 shows the extrusion-lamination plant.
Figure 3 shows diagrammatically the structured surface of the laminate as a result of microscopic or macroscopic embossing.
20 Figure 4 shows a micrograph of the upper side of the laminate.
Figure 5 shows a micrograph of the lower side of the laminate.

Examples

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Example 1

In Figure 1 the laminate is composed of three layers, an outer layer (16), a tie layer (15) and a textile sheet, i.e. a nonwoven (1).

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The outer layer (16) of the laminate is composed of a mixture of a thermoplastic polyolefin (MI (melt index) = 3.5 dg/min; density δ = 0.875 g/cm³ (ASTM D-1505)) and of an LDPE (MI = 2.5 dg/min; density δ = 0.916 g/cm³ (ASTM D-1505)) in a ratio of 90 to 10. The polymer mixture is melted in the extruder together with 5%
35 by weight of a ready made PE colour batch.

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The tie layer (15) of the laminate is composed of a thermoplastic polyolefin (MI = 3.5 dg/min; density δ = 0.875 g/cm³ (ASTM D-1505)) and is melted in a second extruder.

5 The textile sheet (1) is composed of a spun nonwoven made from VLDPE or from a mixture of VLDPE and VLLDPE. It has a macroscopic diamond-shaped embossed effect, as illustrated in Figure 5 (lower side of the laminate). Other properties of the nonwoven material are described in Table 1.

10 TABLE 1: PHYSICAL PROPERTIES OF THE NONWOVEN MATERIAL

Property	Method	Value measured
Weight per unit area	EN 29073 T1	50 g/m ²
Ultimate tensile strength longitudinal transverse	EN 29073 T1	44 N/5 cm 23 N/5 cm
Elongation longitudinal transverse	EN 29073 T1	194% 190%
Titre	DIN 53 811	3.5 dtex

15 The structured surfaces obtained by giving the laminate a microscopic or macroscopic embossed effect, shown in Figure 3, are classified as:

- Stinflex and Velvaflex (51)
- Taffaflex (52)
- Mayaflex (53)

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Figure 2 shows the extrusion-lamination plant.

25 The two polymer melts for the outer layer and tie layer are brought together in the feed block of the extruder (41) and shaped in the slot dye (42). The ratio of outer layer (16) to tie layer (15) here is about 70 to 30, and the weight per unit area of the polymer film is about 50 g/m². The temperature of the slot dye is from 240 to 260°C.

The laying of the two-layer molten film on the nonwoven (1), which is conveyed via an unwind unit (2), is carried out in such a way that the tie layer (15) comes into contact with the nonwoven (1) and the outer layer (16) comes into contact with the cooled engraved roll (34) in the calender unit (31). The contact with the engraved roll (34) provides the outer layer (16) with a microscopic diamond-shaped embossed effect, illustrated in Figure 4 (upper side of the laminate). The macroscopic embossed effect, which is four times larger, of the nonwoven (1) is also reproduced in the finished laminate (11), and it is therefore possible to detect and to feel, on the upper side of the film, a transferred microscopic/macrosopic embossed effect of the same Velvaflex pattern. As a result of this the laminate (11) gives a higher-quality impression.

The laminate (11) is finally wound up.

15 The thickness of the laminate (11) is markedly smaller at the emboss points of the nonwoven (1) (partly melted fibres). The impression given is that the entire laminate (11) has both a microscopic and a macroscopic embossed effect. This results in a softer textile handle of the laminate (11), both on the film side and for the nonwoven side.

20 As this structure gives very good enclosure of the fibres of the nonwoven (1), the result is a perfect composite of the two components, film and nonwoven. Even when elongation is extreme, no delamination of the composite material occurs.

25 The composite material described is characterized by further parameters (see Table 2).

30 The present laminate (11) was coated with pressure-sensitive adhesives of acrylate type or natural-rubber type. Plaster strips (19 mm x 72 mm) were stamped out under standard fabricating conditions with application of a wound pad.

Example 2

35 The outer layer (16) of the laminate is composed of a thermoplastic polyolefin (MI (melt index) = 3.5 dg/min; density δ = 0.875 g/cm³ (ASTM D-1505)), which is

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melted in the extruder together with a ready made PE colour batch (5% by weight).

The tie layer (15) of the laminate is composed of a thermoplastic polyolefin (MI = 5 3.5 dg/min; density δ = 0.875 g/cm³ (ASTM D-1505)), which is melted in a second extruder.

The nonwoven material used is the same as that in Example 1.

10 The ratio of outer layer to tie layer here is about 60 to 40, and the weight per unit area of the polymer film is about 50 g/m².

The extrusion conditions chosen are as for Example 1.

15 The composite material described is characterized by further parameters (see Table 2).

Example 3

20 The outer layer (16) of the laminate is composed of a mixture of a thermoplastic polyolefin (MI (melt index) = 3.5 dg/min; density δ = 0.875 g/cm³ (ASTM D-1505)) and an LDPE (MI = 2.5 dg/min; density δ = 0.916 g/cm³ (ASTM D-1505)) in a ratio of 80 to 20. The polymer mixture is melted in the extruder together with 5% by weight of a ready made PE colour batch.

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The tie layer (15) of the laminate is composed of a thermoplastic polyolefin (MI = 3.5 dg/min; density δ = 0.875 g/cm³ (ASTM D-1505)), which is melted in a second extruder.

30 The nonwoven material used is the same as that in Example 1.

The ratio of outer layer to tie layer here is about 60 to 40, and the weight per unit area of the polymer film is about 50 g/m².

The extrusion conditions chosen are as for Example 1.

35 The composite material described is characterized by further parameters (see Table 2).

Example 4

Only one layer of a PE polymer is used for the lamination.

5 The polymer layer (16) of the laminate is composed of a thermoplastic polyolefin (MI (melt index) = 3.5 dg/min; density δ = 0.875 g/cm³ (ASTM D-1505)). The polymer is melted in the extruder together with 4% by weight of a ready made PE colour batch.

The nonwoven material used is the same as that in Example 1.

10 The weight per unit area of the polymer film is about 50 g/m².

The extrusion conditions chosen are as for Example 1.

15 The composite material described is characterized by further parameters (see Table 2).

Example 5: comparative product, non-elastic laminate

20 The lamination of the nonwoven material of Example 1 here was carried out using conventional LDPE grades.

The outer layer (16) of the laminate is composed of an LDPE polymer (MI (melt index) = 12 dg/min; density δ = 0.916 g/cm³ (ASTM D-1505)). The polymer is melted in the extruder together with 5% by weight of a ready made PE colour batch.

25 The tie layer (15) of the laminate is composed of an LDPE polymer (MI = 12 dg/min; density δ = 0.916 g/cm³ (ASTM D-1505)), which is melted in a second extruder.

30 The nonwoven material used is the same as that in Example 1.

The ratio of outer layer to tie layer here is about 60 to 40, and the weight per unit area of the polymer film is about 60 g/m².

35 The extrusion conditions are as follows: The temperatures for the extruder and the slot dye are set at 280°C.

The composite material described is characterized by further parameters (see Table 2).

TABLE 2: COMPARATIVE OVERVIEW OF PHYSICAL DATA OF THE LAMINATES
PRODUCED IN EXAMPLES 1 TO 5

Parameter / Method	Unit	Example 1	Example 2	Example 3	Example 4	Example 5 (Reference)
Weight per unit area / DIN 53352	g/m ²	108.1	105.7	107.3	104.4	112.5
Tensile force - longitudinal Force for 10% elongation for 50% elongation for 100% elongation	N/inch	11.9 20.2 24.5	11.4 19.9 24.3	11.6 19.7 23.8	9.9 16.8 20.5	18.3 26.2 29.7
Tensile force - transverse Force for 10% elongation for 50% elongation for 100% elongation	N/inch	6.5 12.2 15.1	6.7 12.6 15.5	6.7 13.1 16.4	6.1 11.5 14.4	14.3 20.5 23.0
/ ASTM D-882						
Permanent deformation longitudinal *) for 50% elongation for 100% elongation for 150% elongation	%	0 10 40	0 10 32	0 16 36	0 10 36	0 26 60
Permanent deformation transverse *) for 50% elongation for 100% elongation for 150% elongation	%	0 10 32	0 10 26	0 10 30	0 10 26	0 27 70
Delamination		none	none	none	none	slight

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*) Permanent deformation: Permanent deformation of the specimen in % occurring after elongation by x % of its initial length. The elongation is maintained for 30 seconds and the specimen is then released.

Comparison of Examples 1 to 5

The laminates from Examples 1 to 4 show low levels of plastic deformation after, respectively, 50 and 100% elongation, either in a longitudinal or in a transverse direction, and this proves to be advantageous in the use of these laminates. The comparative material (conventional PE laminate, Example 5) shows, in contrast, markedly higher plastic deformation.

Comparatively small forces are required to achieve small elongations (respectively 10 and 50%) in the laminates of Examples 1 to 4. This is a decisive factor for comfort in the final product. In the comparative material made from conventional LDPE (Example 5), in contrast, markedly higher forces are required to achieve the same elongation.

The composite of the laminate materials of Examples 1 to 4 cannot be separated, even when elongation is very high. The material of Example 5, in contrast, exhibits slight delamination at very high elongation.

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